K083781

FEB -4 2009

# 510(k) Summary of Safety and Effectiveness

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| SUBMITTER: | Surgical Devices, a global business unit<br>of Tyco Healthcare Group LP (d/b/a Covidien)<br>60 Middletown Avenue<br>North Haven, CT 06473<br>Tel. No.: (203) 492-6060 |
| CONTACT PERSON: | Frank Gianelli<br>Senior Associate, Regulatory Affairs |
| DATE PREPARED: | December 18, 2008 |
| TRADE/PROPRIETARY NAME: | EEA™ Hemorrhoid Stapler and accessories |
| COMMON/USUAL NAME: | Surgical Stapler with Implantable Staple |
| CLASSIFICATION NAME: | Staple, Implantable |
| PREDICATE DEVICE(S): | Autosuture™ DST Series™ EEA™ Surgical Stapler (K062850)<br>Ethicon Endo-Surgery Proximate® PPH Hemorrhoidal Circular Stapler and Accessories (K051301) |
| DEVICE DESCRIPTION: | The EEA™ Hemorrhoid stapler is designed for use as a stapling instrument for control of hemorrhoid disease. The instrument places a circular, double-staggered row of titanium DST™ staples. The EEA™ Hemorrhoid Stapler is offered in a 33mm diameter and with 3.5mm and 4.8mm staple sizes.<br><br>The accompanying accessories are comprised of a purse-string suture Anoscope, a Port, and a Dilator. |
| INTENDED USE: | The EEA™ Hemorrhoid Stapler and accessories have application throughout the anal canal to perform surgical treatment of hemorrhoidal disease.<br><br>The EEA™ Hemorrhoid Stapler and accessories can also be used in the lower alimentary tract for the creation of end-to-end and end-to-side anastomosis. |
| TECHNOLOGICAL CHARACTERISTICS: | The EEA™ Hemorrhoid Stapler and accessories are substantially equivalent to the predicate devices with regard to the stapling technologies. |
| MATERIALS: | All components of the EEA™ Hemorrhoid Stapler and accessories are comprised of materials, which are in accordance with ISO Standard 10993-1. |
| PERFORMANCE DATA: | In-vitro, in-vivo and ex-vivo performance evaluations were completed to verify that the EEA™ Hemorrhoid Stapler and accessories are safe and effective and perform as intended. |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB - 4 2009

Surgical Devices d/b/a Covidien
% Mr. Frank Gianelli
Senior Associate, Regulatory Affairs
60 Middletown Avenue
North Haven, Connecticut 06473

Re: K083781
Trade/Device Name: EEA™ Hemorrhoid Stapler and accessories
Regulation Number: 21 CFR 878.4750
Regulatory Class: II
Product Code: GDW
Dated: December 18, 2008
Received: December 19, 2008

Dear Mr. Gianelli:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indications For Use

510(k) Number (if known): K083781

Device Name: **EEA™ Hemorrhoid Stapler and accessories**

Indications For Use:

The EEA™ Hemorrhoid Stapler and accessories has application throughout the anal canal to perform surgical treatment of hemorrhoidal disease.

The EEA™ Hemorrhoid Stapler and accessories can also be used in the lower alimentary tract for the creation of end-to-end and end-to-side anastomosis.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark A Milliken

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083781